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Please quote our reference in any reply.
JMRAPR43

Our ref: VMD675A

To those organisations on the attached list

5 May 1993

Dear Sir/Madam

DEREGULATION AND VETERINARY MEDICINES

You are probably aware of the Government's deregulation initiative which requires all Departments to review the ways in which regulatory requirements are operated to ensure that they achieve their objectives without being more burdensome on industry than is necessary.

The attached paper "Deregulation Plan for Veterinary Medicines" sets out a deregulation strategy for veterinary medicines which aims to meet the requirements of MAFF Ministers whilst ensuring that the safeguards of the regulatory system are not compromised. It covers the purpose of a regulatory system for veterinary medicines, considers the policy objectives for the deregulation of veterinary medicines, summarises the progress to date and outlines what is planned for the future. Much of the work in the document is already in hand and the legislation relating to the European Community will not be completed until 1995 at the earliest.

Ministers are anxious that a wide range of views should be taken into account and if you have any comments on the strategy I would be grateful if they could be sent to Mr C Bean at the VMD by 16 June.

In order to help inform debate on the issues raised by this letter, we intend to make copies of the responses received publicly available at the end of the consultation period. They will be available from the main Ministry Library at 3 Whitehall Place, London SW1A 2HH (telephone 071-270-8421) who will supply copies on request to personal callers or telephone enquirers who may reproduce further copies. It will be assumed, therefore, that your response can be made publicly available in this way unless you clearly indicate that you wish all or part of your response to be excluded from this arrangement.

Yours faithfully

J. M. Rutter

J M RUTTER
Veterinary Medicines Directorate

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DEREGULATION PLAN FOR VETERINARY MEDICINES

SUMMARY

This note sets out the proposed deregulation plan for veterinary medicines as part of the programme of the Ministry of Agriculture, Fisheries and Food to meet the Government's deregulation initiative. It covers the purpose of a regulatory system for veterinary medicines, considers the policy objectives for the deregulation of veterinary medicines, summarises the progress to date, and outlines what is planned for the future.

PURPOSE OF A REGULATORY SYSTEM FOR VETERINARY MEDICINES

1. Therapeutic and prophylactic veterinary medicines are used to treat or prevent diseases in farm and companion animals and thereby improve animal health and welfare. In order to be effective, many veterinary medicines have to contain potentially hazardous chemicals or microorganisms, and the risks of using them have to be balanced against the benefits they confer. The main purpose of a regulatory system for veterinary medicines is to protect public health, including animal health and welfare, and environmental safety. The regulatory procedures provide assurances on food safety for consumers, and give confidence to the users of veterinary medicines that licensed products are safe, of good quality and effective as required by the 1968 Medicines Act and Community legislation. Issue of the product licence demonstrates that the Medicines Act criteria have been met and, as a result, significant benefits accrue to those who manufacture and market veterinary medicines, because products can be sold with this official "seal of approval".

2. The regulation of veterinary medicines is achieved by a system of licences and controls over their sale, supply or import under the Medicines Act 1968 and associated subordinate legislation. The Veterinary Medicines Directorate (VMD) is a Next Steps Executive Agency in the Ministry of Agriculture, Fisheries and Food which has as its aim to ensure the safety, quality and efficacy of veterinary medicines in the UK. To that end it is responsible for the licensing and control of the manufacture and marketing of animal medicines, post-licensing surveillance of suspected adverse reactions and veterinary residues in meat, and the provision of policy advice on these matters to the Agriculture and Health Ministers, who are the Licensing Authority in the UK.

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3. The phased introduction of EC legislation is leading to greater harmonisation of authorisation procedures throughout the Community, but for veterinary medicines this programme will not be completed until 1995 at the earliest. In principle, the animal medicines industry supports these harmonisation measures because they should facilitate trade and lead to cost savings in the preparation of applications for new products on a Community wide basis.

POLICY OBJECTIVES FOR THE DEREGULATION OF VETERINARY MEDICINES

4. The policy objectives of the deregulation initiative as it applies to veterinary medicines are to ensure that measures to be adopted are proportional to the purpose of the regulatory system, and that the burden imposed on the industry is minimised whilst maintaining the safeguards of the licensing system. The Ministry has established five broad principles to be considered when proposals for legislation or reviewing existing legislation are submitted to Ministers. These are:

a) the regulatory approach will be followed only where fully justified and where some less burdensome route (e.g. through codes of conduct) is seen to be inadequate;

b) all EC and national regulations will be examined against strict need criteria and in the case of legislation arising out of EC applications the principle of subsidiarity agreed at the Edinburgh summit;

c) the EC Commission will be asked to produce cost compliance assessments for appropriate new proposals for EC legislation, and Government Departments will produce such assessments for all proposed national legislation;

d) in implementing Community law, the Government will seek to ensure that UK industry is not placed at a disadvantage compared with its competitors in other member states;

e) business representatives will be fully consulted at the earliest possible stage on the effect of proposed new regulations on their own sectors.

The deregulation plan for veterinary medicines will consider existing regulations against these principles during 1993/94 and apply them to future regulations.

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PROGRESS TO DATE

5. The current regulatory procedures for veterinary medicines encompass a number of the principles set out above. For example, consultation on proposed legislation, whether national or EC, has been standard practice for many years. Progress on deregulation to date can be considered under three broad headings - increased harmonisation, increased efficiency of the regulatory procedures and easing of existing legislation.

6. Increased harmonisation

Increased harmonisation has been achieved through the implementation of a series of EC Directives and Regulations. These include Directive 81/851/EEC setting out the multistate procedure for applications for veterinary pharmaceutical products, Directive 87/22/EEC covering products derived from biotechnology, and Regulation 2377/90 for setting Community maximum residue limits for all active ingredients of veterinary medicines after 1992. The aim of these procedures is to facilitate a more harmonised Community approach to licence applications for veterinary products thereby reducing the burden to industry.

7. Increased efficiency of regulatory procedures

The single most important step to improve the efficiency of the regulatory procedures for veterinary medicines in the UK was the establishment of the Veterinary Medicines Directorate (VMD) in 1989, bringing together the professional and administrative licensing staff in a single Directorate. This led to the establishment of the VMD as a Next Steps Executive Agency in 1990, with the setting of demanding performance and financial targets by Ministers for the work of the VMD, and monitoring progress towards the achievement of those targets. Summaries of highlights of progress taken from the 1990/91 and 1991/92 Annual Reports of the VMD are shown at Annex 1.

8. A number of other measures have been introduced to increase the efficiency of the licensing process and thereby reduce the burden on industry, and good progress has been made during the last three years in the following areas:

Liaison Regular liaison meetings are held with the National Office of Animal Health (NOAH) representing the animal medicines industry, with the British Veterinary Association (BVA) representing the veterinary profession, with representatives of consumer organisations, and with other organisations involved in the distribution or use of veterinary medicines.

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These have led to valuable exchanges of information about the work of the VMD and its funding, and to helpful feedback about the quality of service being offered by the Directorate. In particular, a joint VMD/NOAH programme is now underway to identify concerns perceived by the veterinary pharmaceutical companies with the licensing process in the UK, and concerns perceived by the Directorate in the dossiers submitted for registration by the companies. Resolution of the problems identified should lead to further improvements in the efficiency of licensing procedures.

Transparency The initiatives described above have been accompanied by much greater openness about the activities of the VMD. This includes publication of the VMD's Annual Report and Accounts, its Corporate Plan, quarterly publication of the Medicines Act Veterinary Information Service, involvement with NOAH in developing QEST (Quality, Efficacy and Safety through Transparency - an industry proposal to make available more information about newly licensed veterinary medicines), publication of press notices about the work of the Veterinary Products Committee (VPC), the independent expert committee that advises the Licensing Authority, and making available VPC papers which are not commercial in confidence.

QA/QC A Quality Assurance/Quality Control scheme was introduced by the VMD in 1991 in co-operation with the industry, to replace batch testing of immunological products by arrangements that are less expensive and more effective.

Guidelines and Codes of Practice The VMD has contributed significantly to the development of EC Guidelines, which set out the requirements for information to accompany applications for the licensing of veterinary medicines on a Community wide basis. At the national level, codes of practice have been introduced, e.g. for the safe use and disposal of sheep dips in co-operation with HSE.

9. Easing of Existing Legislation

A number of deregulatory steps have been taken with the aim of reducing the burdens on industry without compromising the safeguards of the licensing system:

- a simplified licensing procedure was introduced in 1990 for well known active ingredients in pharmaceutical products with a limited market where animal welfare problems could arise if licensed products were not available;

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- exemption of pet shops from registration for small volume sales of medicated feed for pet animals came into effect in 1992;

- the easing of certification requirements for certain imported feeds came into effect in 1992;

- within the Community, the UK has resisted the introduction of an additional criterion to the licensing requirements which would introduce an assessment of need to the existing scientific criteria of safety, quality and efficacy;

- regulations easing the restrictions on the use of antibiotics in semen for artificial insemination came into effect early in 1993.

PLANS FOR THE FUTURE

10. The deregulation principles set out in para 4 will be applied in three main areas in the future.

Repeal/Easing of Existing Legislation

- Repeal of the Therapeutic Substances Order will take place during the summer of 1993. This will remove the need for an additional licence for certain immunological products.

- Repeal of the Sera and Glandular Products Order will take place during the summer of 1993. This will remove the need to label certain products as being free from specified diseases.

- Exemptions for medicines for certain minor non food-producing species (including aquarium fish) are being considered with a view to implementation during 1993.

- Implementation of Directive 90/676/EEC amending 81/851/EEC is proving to be a major task and some elements will be implemented during the summer of 1993. On present plans some 13 Orders will replace 20 existing Orders, and a review of the Medicines Act/EC legislation will take place to ascertain whether a simpler approach is possible to reduce the legislative burden and ensure consistency between national and EC legislation.

- Draft proposals for simplifying the fees legislation for applications for veterinary medicines in the UK are in hand for introduction in April 1994.

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- New arrangements for setting fees for merchants by the Royal Pharmaceutical Society of Great Britain to a common date with one SI are in hand for introduction during 1994.

11. New legislation

- Community Proposals for Future Systems for the Licensing of Veterinary Medicines will not be completed and lead to the setting up of the European Medicines Evaluation Agency until 1995 at the earliest. The new Agency will issue Community licences, and the current multistate procedure will be modified to allow binding arbitration by the Community's Committee on Veterinary Medicinal Products. These changes will, however, lead to the issue of Community licences and arbitration on a Community basis that should ease the regulatory burden on companies wishing to market a veterinary medicine in up to 12 member states and provide greater trade prospects for UK companies.

- consideration of whether new UK legislation is required to implement EC MRL Regulations is in hand;

- any proposed legislation on the distribution of veterinary medicines within the Community will be carefully examined to ensure that the principles of subsidiarity and the need to avoid unnecessary bureaucracy are fully taken into account;

12. Increased efficiency of the regulatory procedures

Initiatives to improve the efficiency of the licensing procedures will continue during 1993-94 in the following areas:

- the introduction of new IT systems for licence management from April 1993;

- further improvements to the efficiency and quality of service offered by the VMD through meeting the principles of Citizens Charter and Chartermark;

- market testing of selected services will be put in hand to maintain improvements in the efficiency of the Agency.

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13. CONCLUSIONS

Good progress has been made during the last three years in improving the efficiency of the licensing procedures in the UK and increasing the transparency of the regulatory procedures. This has been accompanied by some easing of existing legislation. Initiatives will continue within the resources available to ensure that the regulatory system for veterinary medicines meets its public health and other objectives at both national and Community level without proving to be unnecessarily burdensome to the industry it is seeking to regulate. This should create more business opportunities for the industry whilst reducing the volume of existing and new legislation. Progress will be reported in the Annual Reports and Accounts of the VMD.

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HIGHLIGHTS OF PROGRESS IN 1990/91

Targets achieved

- Full costs recovered for all sectors of VMD's business
- VMD's operating costs held below forecast enabling the Graded Annual Fee to be reduced from 0.61% to 0.59%
- Number of licence applications processed within the target period of 120 clock days increased by 15% over 1989/90
- Fees for residue testing introduced by 1 January 1991

Improvements in service

- Number of licences issued increased by 92% over 1989/90
- Contracts being developed with customers and service providers specifying the nature of the service, delivery standards and costs
- QA/QC inspection scheme developed for biological products, to replace post-licensing batch testing, and introduced from 3 April 1991
- Revised ATX scheme developed and introduced from 3 April 1991
- Confirmatory tests carried out on all samples for residue testing
- IT system for residues in meat developed and introduced on 3 April 1991 to improve sample management and enable results to be made available more quickly
- Grade 5 posts redesignated to clarify responsibility for achieving business targets
- Fee structure for 1991/92 in place by 3 April 1991 compared with 2 July 1990 for 1990/91 fees
- Computerised debt recovery introduced in March 1991

Improvements in liaison

- Quarterly liaison meetings established with the National Office of Animal Health representing the veterinary pharmaceutical industry
- Biannual liaison meetings established with the British Veterinary Association
- Presentations and briefings to consumers and others with an interest in veterinary medicines
- Establishment of clear procedures for direct contact with Members of Parliament in dealing with day to day matters affecting their constituents
- Correspondents kept informed of the outcome of enquiries into alleged uses of unlicensed medicines and misleading claims

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Publicity

- Brochure describing the work of the VMD published in April 1990
- Framework Document setting out the aims, objectives and targets of the VMD, published in April 1990
- Pre-agency Annual Report for 1989/90, describing the work of the Directorate, setting out accounts and reporting residue monitoring results published in December 1990
- Regular contributions made to Medicines Act Information Letter (MAIL) and Food Safety Directorate Information Bulletin on aspects of the VMD's work
- Copies of non commercial-in-confidence papers considered by the Veterinary Products Committee (VPC) made available to the public
- Regular presentations by VMD staff at national and international conferences

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HIGHLIGHTS OF PROGRESS IN 1991/92

Targets achieved

* Overall full cost recovery achieved.
* Overall efficiency saving of 8.3% and a further 8.3% efficiency gain achieved against a target of 2%.

Improvements in Service

* Number of new licences determined increased by 7% over initial forecast and by 60% over 1990/91.
* 104 review licences issued compared with 72 in 1990/91.
* New system of QA/QC inspections for biological products introduced.
* Commercial accrual accounting systems introduced.
* Licensing fees structure reviewed.
* Management responsibility for Research and Development work on veterinary medicines transferred to VMD.
* First full year of charges for monitoring of residues in meat completed.

Improvements in Liaison and Publicity

* Advice leaflet and poster on sheep dips produced and circulated.
* Non commercial-in-confidence papers considered by the Veterinary Products Committee (VPC) made publicly available.
* Guidelines on production of bacterial vaccines published.
* VMD Corporate Plan published.
* Contributions made to Medicines Act Information Leaflet (MAIL) and Food Safety Directorate Information Bulletin on aspects of VMD's work.
* Presentations by VMD staff at national and international conferences.
* Nine statutory instruments introduced following public consultation.
* Inaugural liaison meeting held with representatives of consumer organisations.

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